

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)	
)	
Hubert JANSEN et al.)	Group Art Unit: 3761
)	
Application No.: 10/791,869)	Examiner: WIEST, PHILIP R
)	
Filed: March 4, 2004)	
)	
For: SELF-SEALING MEDICAL FLUID)	Confirmation No.: 5244
TRANSFER DEVICE)	

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Applicant requests a pre-appeal brief review of the rejections set forth in the final Office Action mailed October 20, 2008, the period for response to which has been extended through April 20, 2009 by the three month extension of time and fee filed concurrently herewith. Applicant respectfully asserts that (1) the application has been at least twice rejected; (2) this request is being filed concurrently with a Notice of Appeal; (3) this request is being filed prior to an Appeal Brief; and (4) this request is five or less pages in length, all in accordance with the guidelines set forth in the Official Gazette Notice of July 12, 2005. Applicant requests the prompt review of the Examiner's rejections set forth in the final Office Action.

The Finality of the Rejections of Claim 34 Under 35 U.S.C. § 102(b) is Improper

As an initial matter, claim 34 stands rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,374,264 to Wadsworth (hereinafter "Wadsworth") and by U.S. Patent No. 5,895,383 to Niedospial (hereinafter "Niedospial"). Claim 34 was not previously rejected by Wadsworth or Niedospial and was not amended during prosecution. As the

Examiner previously failed to address claim 34 and now rejects it on new grounds, not necessitated by Applicant's amendments filed July 2, 2008, the finality of these rejections is improper. M.P.E.P. § 706.07(a).

35 U.S.C. § 102(b) Rejections

Claims 12-19, 21, 24-29, and 34 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Niedospial. Applicant respectfully traverses this rejection.

Independent claim 12 requires, in part, that “the sealing portion contacting the piercing portion [has] a diameter greater than a diameter of the piercing portion.” The Examiner states that section 113 and surrounding areas of Niedospial are a sealing portion and that sharp tip 116 is a piercing portion. Office Action at 2. Niedospial does not disclose the diameter of annular groove 113 as bigger than sharp tip 116. Specifically, Niedospial is silent with respect to the dimensions of annular groove 113 and sharp tip 116. The Examiner cannot rely on dimensions of figures within a reference without some disclosure in the prior art that those figures are to scale. *See* M.P.E.P. § 2125. In addition, even if the Examiner could rely on the drawings within Niedospial, which is not proper, the drawings do not support the Examiner's position. Without an explicit disclosure within Niedospial, the Examiner is making an inherency argument regarding relative diameters but has not provided an appropriate analysis for such an argument, i.e., that the inherent characteristic is necessarily present, as is required under M.P.E.P. § 2112 IV. For these reasons alone, Applicant respectfully requests withdrawal of the rejection of claim 12 and its dependent claims 13-19, 21, and 24-29 under 35 U.S.C. § 102(b).

Independent claim 34 recites a fluid transfer device, including, among other things, a sealing portion “extending from the lid section along part of the piercing portion and ending in a

substantially abrupt step, the substantially abrupt step being configured to engage and seal the pierced portion of the elastic stopper when the bead is received in the space”

The Office Action is silent with respect to this required element of claim 34.

Specifically, the Office Action does not address whether Niedospial discloses “a sealing portion ending in a substantially abrupt step, the substantially abrupt step configured to engage and seal the pierced portion of the elastic stopper.” Niedospial does not disclose such features.

Niedospial discloses a cylindrical shaft 112 including an annular groove 113 configured to engage an external ring 69 of stopper 60. Niedospial, col. 5, l. 64-col. 6, l. 5, ll. 32-34.

Niedospial does not show any such engaging or sealing of the pierced portion of the elastic stopper by element 113 (characterized by the Examiner as a sealing portion). As noted by Niedospial, element 69 is an external ring (having an open center through which point 116 of shaft 112 passes) and thus is not a pierced portion of stopper 60. For at least these reasons, Niedospial does not anticipate claim 34.

As noted, claim 34 also stands rejected under 35 U.S.C. § 102(b) as being anticipated by Wadsworth. Claim 34 requires a sealing portion “ending in a substantially abrupt step, the substantially abrupt step being configured to engage and seal the pierced portion of the elastic stopper when the bead is received in the space such that the sealing portion partially enters the elastic stopper.” Wadsworth does not disclose or suggest such features. Wadsworth discloses a fitting 10 for positioning over a liquid entry portion of a culture bottle. Affixed to the center of the body portion 14 of fitting 10 is a needle 26. Through needle 26 extends a lumen 22 in fluid communication with a Luer lock structure 16 at one end and terminating in a sharp point 23 at the other. Wadsworth, col. 2, l. 54-col. 3, l. 2. Wadsworth explicitly discloses “[a]n elastomeric sheath valve 24 preferably is attached to the bottom surface of body portion 14 and surrounds

needle 26, including its point 23.” Wadsworth, col. 3, ll. 3-5. In Wadsworth, needle 23 pierces sheath 24 before penetrating through the septum 45. Sheath 24 is intended to seal needle 23 when no fluid transfer is occurring. Wadsworth does not disclose or suggest that sheath 24 seals the pierced element. Wadsworth, col. 3, ll. 2-11; col. 4, ll. 22-27. Further, Applicant submits that Wadsworth does not disclose a sealing portion partially entering the elastic stopper because the disclosed sealing portion 24 of Wadsworth (which, again, does not seal the pierced element) may contact the top surface of the stopper but travels no farther into the stopper. Wadsworth, Fig. 4. Therefore, Wadsworth does not anticipate claim 34.

Accordingly, for at least these reasons, Applicant respectfully requests reconsideration and withdrawal of the rejections of claim 34 under 35 U.S.C. § 102(b).

35 U.S.C. § 103(a) Rejections

Claim 20 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Niedospial in view of U.S. Patent No. 5,358,501 to Meyer (hereinafter “Meyer”); claims 22 and 23 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Niedospial in view of U.S. Patent No. 3,977,555 to Larson (hereinafter “Larson”); and claims 30-33 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Niedospial in view of U.S. Patent No. 6,558,365 to Zinger et al. (hereinafter “Zinger”). Each of claims 20, 22, 23, and 30-33 depends from claim 12. None of Meyer, Larson, and Zinger, respectively, remedies the deficiencies of Niedospial discussed above with respect to claim 12. Claims 20, 22, 23, and 30-33 are therefore allowable over Niedospial in view of Meyer, Larson, and Zinger, respectively, for at least the same reasons explained above.

Claim 34 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Published Application No. 2002/0121496 to Thiebault et al. (hereinafter “Thiebault”) in view of

Niedospial. Applicant respectfully traverses this rejection and the Examiner's comment that claim 34 "is nearly identical to claim 12." Office Action at 10. Applicant disagrees with this characterization of claim 34 and notes that while claims 12 and 34 may have some features in common, each includes additional features that render it separately patentable.

Independent claim 34 recites a fluid transfer device, including, among other things, a sealing portion ending in a substantially abrupt step "configured to engage and seal the pierced portion of the elastic stopper when the bead is received in the space" Thiebault does not disclose such a feature and this deficiency of Thiebault is not remedied by the disclosure of Niedospial, as previously discussed. Accordingly, for at least this reason, Applicant respectfully requests reconsideration and withdrawal of the rejection of claim 34 under 35 U.S.C. § 103(a).

The Examiner's rejection of the claims includes factual and legal deficiencies with regard to the rejections under 35 U.S.C. § 102(b), 35 U.S.C. § 103(a) and the M.P.E.P. Applicant is therefore entitled to a pre-appeal brief review of the final Office Action. Based on the foregoing arguments, Applicant requests that the rejection of these claims be withdrawn and the claims allowed.

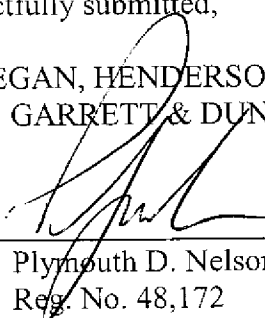
Please grant any extensions of time required to enter this response and charge any additional required fees to our Deposit Account 06-0916.

Respectfully submitted,

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Dated: March 26, 2009

By: _____


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